

REMARKS

This Amendment is submitted in reply to the non-final Office Action dated June 19, 2009 (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on September 19, 2009. Accordingly, this amendment is timely submitted. There are no fees believed due with this Amendment. The Commissioner is hereby authorized to charge Deposit Account No. 50-4498 in the name of Nestle Nutrition for any fees that maybe deemed owed or credit any overpayment.

The Applicant has fully considered the Office Action and cited references and submits this Reply and Amendment in response to the outstanding rejections. Reconsideration of the application for patent is requested. Applicants do not acquiesce in the correctness of the rejections or objections and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further Applicants reserve the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Claims 12-13, 16-21, 24-25 and 27-31 are pending in this application. Claims 1-11, 14-15, 22-23 and 26 were previously canceled without prejudice or disclaimer, and Claim 27 was previously withdrawn from consideration. In the Office Action, Claim 24 is objected to. Claims 12-13, 16-18, 25 and 28-31 are rejected under 35 U.S.C. §102. Furthermore, Claims 12, 16-21, 25 and 28-31 are rejected under 35 U.S.C. §102. In response, Claims 12-13, 16, 18, 28-29 and 31 have been amended and Claim 25 has been canceled. These amendments do not add new matter. At least in view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the rejections should be withdrawn.

In the Office Action, Claim 31 is rejected under 35 U.S.C. §102(e) as being anticipated by International Patent Publication No. WO 2004-002495 to Angstrom et al. ("*Angstrom*"). In response, Applicant has amended independent Claim 31. At least in view of the amendment and/or for the reasons set forth below, Applicant respectfully submits that *Angstrom* fails to disclose every element of independent Claim 31.

Currently amended independent Claim 31 recites, in part, a method of treating acute or chronic pathogenic bacteria-associated, enteric disorders in a mammal, said method comprising administering to said mammal a composition comprising a therapeutically effective amount of a compound selected from the group consisting of caseinoglycomacropeptides (CGMP), chito-oligosaccharides, and combinations thereof, wherein the therapeutically effective amount of the compound is between about 1 g and about 15 g. This amendment does not add new matter.

The amendment is supported in the Specification at, for example, page 5, paragraph 67, lines 1-8; paragraph 69, lines 1-5; page 8, paragraphs 101-102 (Examples 5-6). In contrast, Applicant respectfully submits that *Angstrom* fails to disclose every element of Claim 31.

For example, *Angstrom* fails to disclose or suggest administering a composition comprising a therapeutically effective amount of a compound selected from the group consisting of caseinoglycomacropeptides (CGMP), chito-oligosaccharides, and combinations thereof, wherein the therapeutically effective amount of the compound is between about 1 g and about 15 g as required, in part, by independent Claim 31. The Patent Office asserts that *Angstrom* discloses a composition containing a pathogen-binding oligosaccharide for treating infections caused by pathogenic *E. coli* and *Helicobacter* species. See, Office Action, page 5, lines 3-5. The Patent Office further asserts that the compositions anticipate Claim 31 because *Angstrom* teaches that the compositions can "additionally" include prebiotic oligosaccharides such as chitosan. See, Office Action, page 5, lines 6-8. However, the portion of *Angstrom* relied on by the Patent Office merely discloses that "[t]he present invention is also directed to the use of other polysaccharides which are used in food or for nutritional purposes such as chitosan or beta-glucans for example glucan from oats, which are used to reduce cholesterol and fats." See, *Angstrom*, page 85, lines 26-29. Nowhere does *Angstrom* disclose or suggest administering a therapeutically effective amount of the compound between about 1 g and about 15 g, nor does the Patent Office cite support for such claimed element. In fact, *Angstrom* is entirely directed to administering specific oligosaccharide sequences and combinations of sequences to treat diarrhea and merely teaches optionally including chitosan as an additional substance for its known prebiotic effects. See, *Angstrom*, page 1, lines 5-21; page 2, lines 5-17; page 85, lines 13-29. For example, *Angstrom* states that "[i]n a separate embodiment at least two pathogen inhibiting oligosaccharides are administered together with a probiotic microbe and/or a prebiotic substance. . . . [t]he prebiotic substances also include polysaccharides. . . such as inulin or modified starches. The present invention is also directed to the use of other polysaccharides. . . such as chitosan." See, *Angstrom*, page 85, lines 13-14 and 25-29. As such, one of ordinary skill in the art would understand that *Angstrom* merely teaches using chitosan as an additional substance in its composition along with the pathogen inhibiting oligosaccharides and fails to teach administering a therapeutically effective amount of chitosan to treat pathogenic bacteria-associated, enteric disorders. Thus, *Angstrom* fails to disclose administering a composition comprising a therapeutically effective amount of a compound selected from the group consisting of caseinoglycomacropeptides (CGMP), chito-

oligosaccharides, and combinations thereof, wherein the therapeutically effective amount of the compound is between about 1 g and about 15 g in accordance with Claim 31.

Accordingly, Applicant respectfully requests that the rejection of Claim 31 under 35 U.S.C. §102(e) to *Angstrom* be withdrawn.

In the Office Action, Claims 12-13, 16-18 and 28-30 are rejected under 35 U.S.C. §102(b) as being anticipated by "Effect of supplements of partially hydrolyzed guar gum on the occurrence of constipation and use of laxative agents" to Patrick et al. ("*Patrick*"). In response, Applicant has amended Claims 12-13, 16, 18 and 28-29. At least in view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that *Patrick* fails to disclose every element of independent Claims 12, 16, 18 and 28-29 and Claims 13, 17 and 30 that depend therefrom.

Currently amended independent Claims 12 and 16 recite, in part, a nutritional or pharmaceutical composition comprising: a first compound selected from the group consisting of methyl manno-oligosaccharides, partially hydrolysed guar gum, and combinations thereof, wherein the composition comprises about 2.5% to about 10% of the first compound by total weight of the composition; and a second compound selected from the group consisting of: proanthocyanidins, lactoferrin, linoleic acid and linolenic acid.

Currently amended independent Claim 18 recites, in part, a method for inhibiting pathogenic bacteria adhesion to mammalian cells or for reducing or inhibiting the invasion and infection of mammalian cells by pathogenic bacteria, the method comprising administering to a mammal a composition comprising: a first compound selected from the group consisting of methyl manno-oligosaccharides, partially hydrolysed guar gum, and combinations thereof, wherein said mammalian cells are those of the gut and intestinal mammalian cells, and wherein the composition comprises about 2.5% to about 10% of the first compound by total weight of the composition; and a second compound selected from the group consisting of: proanthocyanidins, lactoferrin, linoleic acid and linolenic acid.

Currently amended independent Claim 28 recites, in part, a method for the manufacture of a nutritional or pharmaceutical composition for the inhibition of pathogenic bacteria adhesion to mammalian cells, or for reducing or inhibiting the invasion and infection of mammalian cells by pathogenic bacteria, the method comprising adding to the nutritional or pharmaceutical composition a first compound selected from the group consisting of methyl manno-oligosaccharides, partially hydrolysed guar gum, and combinations thereof, wherein the mammalian cells are mammalian gut or intestinal epithelial cells, wherein the composition

comprises about 2.5% to about 10% of the first compound by total weight of the composition; and adding to the nutritional or pharmaceutical composition a second compound selected from the group consisting of: proanthocyanidins, lactoferrin, linoleic acid and linolenic acid.

Similarly, currently amended independent Claim 29 recites, in part, a method for the manufacture of a nutritional or pharmaceutical composition for the treatment of acute or chronic pathogenic bacteria-associated enteric disorders in a mammal or for the treatment of pathogenic bacteria microflora proliferation in the mammal, the method comprising adding to the nutritional or pharmaceutical composition a first compound selected from the group consisting of methyl manno-oligosaccharides, partially hydrolysed guar gum, and combinations thereof, wherein the composition comprises about 2.5% to about 10% of the first compound by total weight of the composition; and adding to the nutritional or pharmaceutical composition a second compound selected from the group consisting of: proanthocyanidins, lactoferrin, linoleic acid and linolenic acid. These amendments do not add new matter. The amendments are supported in the Specification at, for example, page 3, paragraph 45. In contrast, Applicant respectfully submits that *Patrick* fails to disclose every element of the present claims.

For example, *Patrick* fails to disclose or suggest a nutritional or pharmaceutical composition comprising a second compound selected from the group consisting of: proanthocyanidins, lactoferrin, linoleic acid and linolenic acid as required, in part, by independent Claims 12, 16, 18 and 28-29. The Patent Office asserts that *Patrick* discloses a composition containing about 2.5% to about 10% by weight of partially hydrolyzed guar gum. See, Office Action, page 5, lines 14-21. However, *Patrick* is entirely directed to administering partially hydrolyzed guar gum with fluid as a soluble fiber for treating constipation. See, *Patrick*, page 913, column 1, paragraphs 1-4; page 914, column 1, paragraph 5. Nowhere does *Patrick* disclose administering an additional compound such as proanthocyanidins, lactoferrin, linoleic acid or linolenic acid along with its partially hydrolyzed guar gum. Therefore, *Patrick* fails to disclose a second compound selected from the group consisting of: proanthocyanidins, lactoferrin, linoleic acid and linolenic acid as required, in part, by Claims 12-13, 16-18 and 28-30.

With respect to Claim 18, *Patrick* also fails to disclose a method for inhibiting pathogenic bacteria adhesion to mammalian cells or for reducing or inhibiting the invasion and infection of mammalian cells by pathogenic bacteria. The Patent Office admits that *Patrick* does not disclose inhibiting or treating enteral infections but nevertheless asserts that such effects are inherent in any composition containing the recited ingredients. See, Office Action, page 6,

lines 1-7. However, as discussed previously, *Patrick* fails to disclose or suggest a composition containing all the claimed ingredients because it does not disclose that its composition contains a second compound selected from the group consisting of: proanthocyanidins, lactoferrin, linoleic acid and linolenic acid. Moreover, *Patrick* is entirely directed to administering partially hydrolyzed guar gum as a soluble fiber for treating constipation. See, *Patrick*, page 913, column 1, paragraphs 1-4; page 914, column 1, paragraph 5. Thus, *Patrick* fails to disclose or suggest a method for inhibiting or treating the adhesion of or infection by pathogenic bacteria as required, in part, by independent Claim 18.

Accordingly, Applicant respectfully requests that the rejection of Claims 12-13, 16-18 and 28-30 under 35 U.S.C. §102(b) to *Patrick* be withdrawn.

In the Office Action, Claim 31 is rejected under 35 U.S.C. §103(a) as being unpatentable over "Chitosan oligosaccharides, dp 2-8, have prebiotic effect on the *Bifidobacterium bifidum* and *Lactobacillus* sp." to Lee et al. ("*Lee*") in view of U.S. Patent No. 5,906,982 to Prieto et al. ("*Prieto*"). In response, Applicant has amended Claim 31. At least in view of the amendment and/or for the reasons set forth below, Applicant respectfully submits that, even if combinable, the cited references fail to disclose every element of Claim 31.

For example, the cited references fail to disclose or suggest a method of treating acute or chronic pathogenic bacteria-associated, enteric disorders in a mammal as required, in part, by Claim 31. The Patent Office asserts that Lee discloses chitooligosaccharides for stimulating the growth of bifidobacteria. See, Office Action, page 6, lines 18-21. However, Applicant respectfully submits that this portion of *Lee* merely discloses the known prebiotic effects of chitooligosaccharides. See, *Lee*, Title; Abstract; page 320, column 1, paragraph 4 – column 2, paragraph 1. Nowhere does *Lee* disclose the use of chitooligosaccharides to treat pathogenic bacteria-associated, enteric disorders, nor does the Patent Office cite support for such claimed element.

Prieto also fails to disclose a method of treating acute or chronic pathogenic bacteria-associated, enteric disorders in a mammal. The Patent Office asserts that *Prieto* discloses a formulation that is effective for stimulating the growth of bacteria of the genus *Bifidobacterium* and can be used to inhibit infection with bacterial species such as *E. coli*. See, Office Action, page 6, lines 22-23; page 7, lines 1-2. However, the portion of *Prieto* relied on by the Patent Office merely discloses that Lacto-N-neoTetraose (LNnT) can be used to inhibit the growth of Bacteroides, Clostridium, and *E. coli*. See, *Prieto*, column 4, lines 7-15. *Prieto* explains that LNnT can be used to treat or prevent "bacterial infections" based on studies showing that

human breast milk, rather than oligosaccharides, inhibits the growth of *Bacteroides*, *Clostridium*, and *E. coli*. See, *Prieto*, column 4, lines 10-14. However, nowhere does *Prieto* disclose treating pathogenic bacteria-associated enteric disorders. Applicant respectfully submits that one skilled in the art would understand that pathogenic bacteria-associated enteric disorders are distinguishable from the general "bacterial infections" disclosed by *Prieto*.

The Patent Office further asserts that one of ordinary skill in the art would have been motivated to administer the chitooligosaccharides of *Lee* to treat an enteric bacterial infection because *Prieto* "already discloses using a different Bifidobacterium-enhancing prebiotic composition for the same purpose. . . [and] it is well recognized in the art that one known composition can be substituted for another known composition having the same disclosed function and utility." See, Office Action, page 7, lines 3-7. However, even if the Patent Office is correct that *Prieto* discloses using a different Bifidobacterium-enhancing prebiotic composition to treat enteric disorders, Applicant respectfully submits that chitooligosaccharides are not compositions "having the same disclosed function and utility" as LNnT. For example, the only alleged shared function and utility of chitooligosaccharides and LNnT is as a prebiotic for stimulating the growth of bifidobacteria. However, *Prieto* teaches that LNnT can be used to inhibit bacterial infections not based on its function as a prebiotic but rather based on studies showing that human breast milk prevents certain bacterial infections. Therefore, Applicant respectfully submits that one of ordinary skill in the art would have no reason to substitute the prebiotic chitooligosaccharides of *Lee* for the LNnT of *Prieto* to treat acute or chronic pathogenic bacteria-associated, enteric disorders. *Prieto* does not teach that all prebiotics which stimulate the growth of bifidobacteria also treat or prevent bacterial infections; instead, *Prieto* merely teaches that a specific compound, LNnT, stimulates the growth of bifidobacteria and inhibits the growth of *Bacteroides*, *Clostridium*, and *E. coli*. See, *Prieto*, column 4, lines 7-15.

Moreover, the cited references fail to disclose or suggest administering a therapeutically effective amount of a compound selected from the group consisting of caseinoglycomacropolypeptides (CGMP), chito-oligosaccharides, and combinations thereof, wherein the therapeutically effective amount of the compound is between about 1 g and about 15 g. The Patent Office asserts that *Lee* discloses the use of chitooligosaccharides to stimulate the growth of bifidobacteria and that *Prieto* discloses a nutritional formulation that is effective for stimulating the growth of *Bifidobacterium* bacteria and can be used to inhibit infection with *E. coli*. See, Office Action, page 6, lines 18-23; page 7, lines 1-2. However, *Lee* merely discloses the known prebiotic effects of chitooligosaccharides. See, *Lee*, Title; Abstract; page 320,

column 1, paragraph 4 – column 2, paragraph 1. In addition, *Prieto* merely discloses generally that LNT inhibits the growth of *E. coli*. See, *Prieto*, column 4, lines 7-15. Nowhere do the cited references disclose or suggest administering between about 1 and about 15 g of chitooligosaccharides to treat enteric disorders in a mammal. As such, the cited references fail to disclose administering a composition comprising a therapeutically effective amount of a compound selected from the group consisting of caseinoglycomacropeptides (CGMP), chito-oligosaccharides, and combinations thereof, wherein the therapeutically effective amount of the compound is between about 1 g and about 15 g in accordance with Claim 31.

Accordingly, Applicant respectfully requests that the rejection of Claim 31 under 35 U.S.C. §103(a) to *Lee* and *Prieto* be withdrawn.

In the Office Action, Claims 12, 16-18, 25 and 28-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,863,918 B2 to Bindels et al. ("*Bindels*"). In response, Applicant has amended Claims 12, 16, 18 and 28-29 and canceled Claim 25. At least in view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that *Bindels* fails to disclose every element of independent Claims 12, 16, 18 and 28-29 and Claims 13, 17 and 30 that depend therefrom.

For example, *Bindels* fails to disclose or suggest a composition comprising a first compound selected from the group consisting of methyl manno-oligosaccharides, partially hydrolysed guar gum, and combinations thereof, wherein the composition comprises about 2.5% to about 10% of the first compound by total weight of the composition as required, in part, by independent Claims 12, 16, 18 and 28-29. The Patent Office asserts that *Bindels* discloses an infant formula comprising between 3 and 15% of isomalto-oligosaccharides. See, Office Action, page 7, lines 15-22. In response, Applicant has amended Claims 12, 16, 18 and 28-29 to remove the term "long chain isomalto-oligosaccharides" and has canceled Claim 25. Applicant respectfully submits that *Bindels* fails to disclose that its composition includes about 2.5% to about 10% by weight of methyl manno-oligosaccharides, partially hydrolysed guar gum, or combinations thereof. Therefore, Applicant respectfully submits that *Bindels* fails to disclose every element of Claims 12-13, 16-18 and 28-30.

With respect to Claim 18, *Bindels* also fails to disclose a method for inhibiting pathogenic bacteria adhesion to mammalian cells or for reducing or inhibiting the invasion and infection of mammalian cells by pathogenic bacteria. The Patent Office admits that *Bindels* does not disclose compositions for inhibiting or treating enteral infections but nevertheless asserts that such effects are inherent in any composition containing the recited ingredients. See, Office

Action, page 8, lines 5-10. However, as discussed previously, *Bindels* fails to disclose or suggest a composition containing all the claimed ingredients because it does not disclose a composition comprising about 2.5% to about 10% of methyl manno-oligosaccharides, partially hydrolysed guar gum, or combinations thereof as required, in part, by Claim 18. Moreover, *Bindels* is entirely directed to an infant formula with an improved protein content to reduce constipation. See, *Bindels*, Title; Abstract; column 1, lines 4-6. Therefore, *Bindels* fails to disclose or suggest each and every element of Claim 18.

Accordingly, Applicant respectfully requests that the rejection of Claims 12, 16-18, 25 and 28-30 under 35 U.S.C. §103(a) to *Bindels* be withdrawn.

In the Office Action, Claims 12-13, 16-18 and 28-30 are rejected under 35 U.S.C. §102(b) as being anticipated by "The prebiotic effects of biscuits containing partially hydrolysed guar gum and fructo-oligosaccharides – a human volunteer study" to Tuohy et al. ("*Tuohy*"). In response, Applicant has amended Claims 12, 16, 18 and 28-29. At least in view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that *Tuohy* fails to disclose every element of independent Claims 12, 16, 18 and 28-29 and Claims 13, 17 and 30 that depend therefrom.

For example, *Tuohy* fails to disclose or suggest a nutritional or pharmaceutical composition comprising a second compound selected from the group consisting of: proanthocyanidins, lactoferrin, linoleic acid and linolenic acid as required, in part, by independent Claims 12, 16, 18 and 28-29. The Patent Office asserts that *Tuohy* discloses administering biscuits that contain 11% by weight of partially hydrolysed guar gum. See, Office Action, page 9, lines 9-14. However, *Tuohy* is entirely directed to administering partially hydrolysed guar gum and fructooligosaccharides in a biscuit for stimulating the growth of beneficial bacteria. See, *Tuohy*, Abstract; page 341, paragraph 1. Nowhere does *Tuohy* disclose administering an additional compound such as proanthocyanidins, lactoferrin, linoleic acid or linolenic acid along with its partially hydrolysed guar gum. Therefore, *Tuohy* fails to disclose a second compound selected from the group consisting of: proanthocyanidins, lactoferrin, linoleic acid and linolenic acid as required, in part, by Claims 12-13, 16-18 and 28-30.

With respect to Claim 18, *Tuohy* also fails to disclose a method for inhibiting pathogenic bacteria adhesion to mammalian cells or for reducing or inhibiting the invasion and infection of mammalian cells by pathogenic bacteria. The Patent Office admits that *Tuohy* does not disclose using its compositions for inhibiting or treating enteral infections but nevertheless

asserts that such effects are inherent in any composition containing the recited ingredients. See, Office Action, page 9, lines 18-22; page 10, lines 1-2. However, as discussed previously, *Tuohy* fails to disclose or suggest a composition containing all the claimed ingredients because it does not disclose a second compound selected from the group consisting of: proanthocyanidins, lactoferrin, linoleic acid and linolenic acid. Moreover, *Tuohy* is entirely directed to administering partially hydrolysed guar gum in a biscuit merely to analyze its prebiotic effects. See, *Tuohy*, Title; Abstract; page 341, paragraph 1. Nowhere does *Tuohy* disclose a method for inhibiting or treating the adhesion of or infection by pathogenic bacteria, nor does the Patent Office cite support for such claimed element. Therefore, *Tuohy* fails to disclose or suggest each and every element of Claim 18.

Accordingly, Applicant respectfully requests that the rejection of Claims 12-13, 16-18 and 28-30 under 35 U.S.C. §102(b) to *Tuohy* be withdrawn.

In the Office Action, Claims 19-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Tuohy* in view of *Prieto*. For at least the reasons set forth below, Applicant respectfully submits that, even if combinable, the cited references are deficient with respect to the present claims.

For example, the cited references fail to disclose a method of treating acute or chronic pathogenic bacteria-associated, enteric disorders in a mammal as recited, in part, by independent Claim 19. The Patent Office asserts that *Tuohy* discloses using partially hydrolysed guar gum as a prebiotic for stimulating the growth of bifidobacteria and lactobacilli. See, Office Action, page 9, lines 17-18; page 11, lines 1-3. However, Applicant respectfully submits that *Tuohy* merely discloses the known prebiotic effects of partially hydrolysed guar gum. See, *Tuohy*, Title; Abstract; page 341, paragraph 1. As the Patent Office admits, *Tuohy* does not disclose the use of partially hydrolysed guar gum to treat pathogenic bacteria-associated, enteric disorders. See, Office Action, page 11, lines 1-3.

Prieto also fails to disclose a method of treating acute or chronic pathogenic bacteria-associated, enteric disorders in a mammal. The Patent Office asserts that *Prieto* discloses a formulation that is effective for stimulating the growth of bacteria of the genus *Bifidobacterium* and can be used to inhibit infection with bacterial species such as *E. coli*. See, Office Action, page 11, lines 4-7. However, as discussed previously, the portion of *Prieto* relied on by the Patent Office merely discloses that Lacto-N-neoTetraose (LNnT) can be used to inhibit the growth of Bacteroides, Clostridium, and *E. coli*. See, *Prieto*, column 4, lines 7-15. *Prieto* merely teaches that LNnT can be used to treat or prevent "bacterial infections" based on studies

showing that human breast milk, rather than oligosaccharides, inhibits the growth of Bacteroides, Clostridium, and *E. coli*. See, *Prieto*, column 4, lines 10-14. However, nowhere does *Prieto* disclose treating pathogenic bacteria-associated enteric disorders. Applicant respectfully submits that one skilled in the art would understand that pathogenic bacteria-associated enteric disorders are distinguishable from the general "bacterial infections" disclosed by *Prieto*.

The Patent Office further asserts that one of ordinary skill in the art would have been motivated to administer the partially hydrolysed guar gum of *Tuohy* to treat an enteric bacterial infection because *Prieto* "already discloses using a different Bifidobacterium-enhancing prebiotic composition for the same purpose. . . [and] it is well recognized in the art that one known composition can be substituted for another known composition having the same disclosed function and utility." See, Office Action, page 7, lines 3-7. However, even if the Patent Office is correct that *Prieto* discloses using a different Bifidobacterium-enhancing prebiotic composition to treat enteric disorders, Applicant respectfully submits that partially hydrolysed guar gum is not a composition "having the same disclosed function and utility" as LNnT. For example, the only alleged shared function and utility of partially hydrolysed guar gum and LNnT is as a prebiotic for stimulating the growth of bifidobacteria. However, *Prieto* teaches that LNnT can be used to inhibit bacterial infections not based on its function as a prebiotic but rather based on studies showing that human breast milk prevents certain bacterial infections. Therefore, Applicant respectfully submits that one of ordinary skill in the art would have no reason to substitute the prebiotic PHGG of *Tuohy* for the LNnT of *Prieto* to treat acute or chronic pathogenic bacteria-associated, enteric disorders. *Prieto* does not teach that all prebiotics which stimulate the growth of bifidobacteria also treat or prevent bacterial infections; instead, *Prieto* merely teaches that a specific compound, LNnT, stimulates the growth of bifidobacteria and inhibits the growth of Bacteroides, Clostridium, and *E. coli*. See, *Prieto*, column 4, lines 7-15.

Accordingly, Applicant respectfully requests that the rejection of Claims 19-21 under 35 U.S.C. §103(a) to *Tuohy* and *Prieto* be withdrawn.

In the Office Action, Claims 19-21 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Bindels* in view of U.S. Patent No. 6,613,549 B2 to Reid et al. ("*Reid*"). For at least the reasons set forth below, Applicant respectfully submits that, even if combinable, the cited references are deficient with respect to the present claims.

For example, the cited references fail to disclose a method of treating acute or chronic pathogenic bacteria-associated, enteric disorders in a mammal by administering the claimed

composition as recited, in part, by independent Claim 19. The Patent Office asserts that *Bindels* discloses administering a composition comprising 3 to 15% long-chain isomalto oligosaccharides as a prebiotic for stimulating the growth of bifidobacteria. See, Office Action, page 7, lines 15-22. However, Applicant respectfully submits that *Bindels* merely discloses the known prebiotic effects of isomalto oligosaccharides. See, *Bindels*, column 15, lines 16-22. As the Patent Office admits, *Bindels* does not disclose the use of long-chain isomalto oligosaccharides to treat pathogenic bacteria-associated, enteric disorders. See, Office Action, page 12, lines 13-15.

Reid also fails to disclose a method of treating acute or chronic pathogenic bacteria-associated, enteric disorders in a mammal by administering the claimed composition. The Patent Office asserts that *Reid* discloses probiotic formulations such as bifidobacteria for the treatment and inhibition of intestinal infection in newborns. See, Office Action, page 12, lines 16-21. The Patent Office further asserts that one skilled in the art would have been motivated to administer the isomalto oligosaccharides of *Bindels* to treat pathogenic bacteria-associated enteric disorders merely because *Reid* teaches treating the same disorders by improving the population of bifidobacteria in the intestine. See, Office Action, page 13, lines 5-13. However, *Reid* is entirely directed to treating intestinal infections using probiotic microorganisms, rather than prebiotic substances such as isomalto oligosaccharides. See, *Reid*, Title; Abstract; column 3, lines 35-38. Applicant respectfully submits that one of ordinary skill in the art would understand that a probiotic microorganism is entirely distinguishable from a prebiotic substance which stimulates the growth of such probiotic microorganisms. *Reid* merely teaches that certain probiotics can be used to treat or prevent intestinal infections. *Reid* does not teach that all substances which increase the population of bifidobacteria also treat or prevent intestinal infections; instead, *Reid* merely teaches that specific probiotics such as *Lactobacillus* and *Bifidobacteria* help prevent intestinal infection in newborn infants. See, *Reid*, column 3, lines 1-38. Therefore, Applicant respectfully submits that one of ordinary skill in the art would have no reason to substitute the prebiotic isomalto oligosaccharides of *Bindels* for the probiotic organisms of *Reid* to treat acute or chronic pathogenic bacteria-associated, enteric disorders.

Accordingly, Applicant respectfully requests that the rejection of Claims 19-21 under 35 U.S.C. §103(a) to *Bindels* and *Reid* be withdrawn.

The Patent Office states that Claim 24 is objected to as being dependent on a rejected base claim but would be allowable if rewritten in independent form. See, Office Action, page 14,

lines 5-8. In response, Applicant respectfully notes that Claim 24 is an independent claim and, thus, should be allowable in its present form.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly requests an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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